

## REMARKS

The Office Action has imposed a restriction requirement under 35 U.S.C. §121 and 372 as follows:

- |            |  |
|------------|--|
| Group I    | The compound of Claim 34....   |
| Group II   | The compound or composition of the formula Ia, according to Claims 30 and 31.  |
| Group III  | The compound or composition of the formula Ib, according to Claims 30 and 31.  |
| Group IV   | The compound or composition of the formula Ic, according to Claims 30 and 31.  |
| Group V    | The compound or composition of the formula Id, according to Claims 30 and 31.  |
| Group VI   | The compound or composition of the formula Ie, according to Claims 30 and 31.  |
| Group VII  | The compound or composition of the formula If, according to Claims 30 and 31.  |
| Group VIII | The compound or composition of the formula I, not previously mentioned in the above groups, according to Claims 22, and 26-28. |
| Group IX   | The compound of Claim 9, according to Claim 32.  |
| Group X    | A process for the preparation of a compound of formula II defined in Claim 29, according to Claim 33.                          |
| Group XI   | The compound of formula II, according to Claim 29.   |
| Group XII  | A method for the treatment or prophylaxis of a condition, according to Claims 1-19.  |

According to the Office Action, the invention in Groups I-XII do not relate to a single general inventive concept under PCT Rule 13.1 alleging that they lack the same or corresponding special technical feature. The Office Action specifically states as follows:

The technical feature linking the claims is a compound of general formula I. The core structure here is an optionally substituted biaryl-tetraaryl ring system as a core with variables existing all throughout the ring system. The core could be anything from a quinazolinone to a phenanthroline core. Therefore the feature linking the claims does not constitute a special technical feature as defined by PCT Rule 13.2 as it does not define a contribution over the art.

The Office Action concludes that Groups I-XII are not so linked by the same or corresponding special technical feature as to form a single general inventive concept. The Office Action requests applicant to elect an invention for continued examination herein.

In addition, the United States Patent and Trademark Office ("USPTO") has alleged that the claims define patentably distinct species and the Office Action requests applicants to elect a single species for examination.

In order to be responsive to the restriction requirement, applicants elect, with traverse, Group II for continued examination herein. Further, in order to be responsive to the species requirement, applicants elect, with traverse, the species identified as compound 1055 in Claim 9.

Applicants respectfully submit that Claim 32 should be grouped with Group II as there are species in Claim 32, which fall within the scope of the claims of Group II.

Thus, to be responsive to the restriction requirements in the Office Action, with respect to elected Group II, the following claims read thereon: Claims 30, 31, and 32. Moreover, with respect to the species requirement, Claims 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17,

18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33 read on the elected species, compound 1055 . With respect to the claims elected in Group II, the compound 1055 reads on Claims 30, 31, 32.

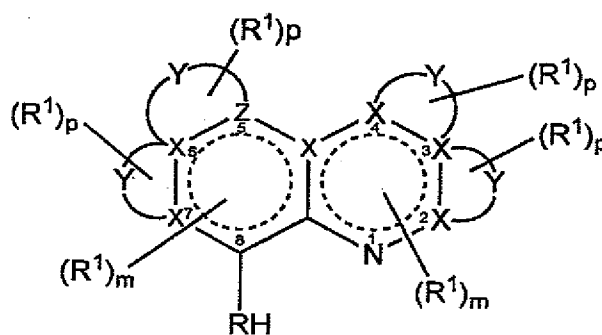
Nevertheless, applicants reserve the right to file a divisional application directed to the non-elected subject matter.

However, pursuant to 37 CFR §§1.111 and 1.143, applicants hereby traverse the Examiner's requirement for restriction and request reconsideration thereof in view of the following Remarks.

Applicants respectfully request that this Restriction Requirement be withdrawn since it is not in compliance with 35 U.S.C. § 121. 35 U.S.C. § 121 provides that the Commissioner may restrict an application when “two or more independent and distinct invention are claimed in a single application.” (Emphasis added).

A requirement for restriction for an international application entering the national stage presupposes an analysis of the subject application in light of the rules governing this practice, i.e., 37 C.F.R. §1.499 and PCT Rules 13.1 and 13.2. PCT Rule 13.1, first sentence, states: “The international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept (‘requirement of unity of invention’).” (Emphasis added.).

Applicants respectfully submit that the claims define a single inventive concept. More specifically, the claims in the present application is defined by the structure, all having a common core as defined below:



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The core structure includes at least two fused rings with a nitrogen atom at position 1 of the ring structure and a RH substituent at position 8 of the ring structure and X at a bridgehead and at positions 2, 3, 4, 6 and 7 of the ring structure, wherein each X is independent and is as defined in Claim 1, and a Z at position 5 of the ring wherein Z is as defined in Claim 1. Additionally, additional fused rings may also be present, as shown in the structure of formula I as defined in Claim 1. The compounds described by formula I are subject to the provisos recited in Claim 1 and the compounds described by formula II is a compound of formula I with proviso described hereinabove and the proviso of Claim 29. All of the compounds have this core structure, and all of the compounds claimed can be defined by this core structure. Furthermore, all the compounds described by this core structure are useful for the treatment, amelioration and/or prophylaxis of a neurological condition. The claims relate to the compounds defined by the structure, the use thereof and the process for making the same. Thus, as defined there is unity of invention.

As part of its rationale for supporting the restriction requirement, the Office Action refers to PCT Rule 13.2, alleging that the claims lack the same or corresponding technical feature. PCT

Rule 13.2 states: "The expression "technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art." (Emphasis added). Here, the Office Action has not provided or discussed any prior art in the Office Action. It merely concludes that the claims do not define a contribution over the prior art without providing prior art and support thereon. Therefore, the USPTO has no basis to conclude that the present invention as a whole, do not define a contribution over the prior art. Therefore, the USPTO has not made a prima facie case to support this restriction requirement.

Furthermore, this restriction requirement is not in compliance with MPEP §808, which states:

Every requirement to restrict has two aspects: (a) the reasons (as distinguished from the mere statement of conclusion) why the invention as claimed are either independent or distinct and (b) the reasons for insisting upon restriction therebetween.

The Office Action has not provided or discussed any prior art therein. It merely concludes that the claims do not define a contribution over the art. Thus, the Office Action with respect to the restriction requirement has not complied with the statute, regulations, or the MPEP. Therefore, it is improper for the Office Action to restrict the subject matter to the various groups.

Moreover, with respect to the species requirement, the restriction requirement is not in compliance with 35 U.S.C. §121. It is respectfully submitted that the Office Action has not made out a prima facie case to support the restriction requirement with respect to species.

In this instance the Office Action has not met its burden as it merely concludes without any rationale, that the species used in the present invention are independent and distinct. The

USPTO has the burden to show that the species are patentably distinct. It has not met its burden.

More specifically, the USPTO has not shown that the various species are independent and distinct, as to justify a Restriction Requirement under 35 U.S.C. § 121. For this reason, the Restriction Requirement is improper and should be withdrawn.

In fact, applicant submits that the various species are not independently and distinct, as defined in 35 U.S.C. 121. MPEP §802.01 defines independent as follows:

The term “independent” (i.e., not dependent) means that there is no disclosed relationship between the two or more subjects disclosed, that is, they are unconnected in design, operation or effect.

The various species are all encompassed by the compound of Formula I. Thus, the various species encompassed by Formula I are therefore very clearly interrelated and interdependent, and are not “independent and distinct”. Thus, because the various species within the scope of Formula I of claims are interdependent, and therefore not independent, they are not “independent and distinct” so as to justify the Restriction Requirement. It is therefore respectfully submitted that the Restriction Requirement is improper and cannot be maintained.

Moreover, this species restriction requirement is also not in compliance with MPEP §808.

MPEP §808 states:

Every requirement to restrict has two aspects: (a) the reasons (as distinguished from the mere statement of conclusion) why the invention as claimed are either independent or distinct and (b) the reasons for insisting upon restriction therebetween.

The Office Action, merely concludes that the species are patentably distinct. It did not provide any reasons why the species are patentably distinct. In addition, it has not provided any

reasons for insisting upon restriction therebetween.

Thus, the Office Action has not complied with the statute, regulations or the MPEP. Therefore, it is also improper for the Office Action to restrict the subject matter to the elected species.

It is vital to all applicants that the restriction requirements with respect to the various groups and species, as alleged in the Office Action, issue only with the proper statutory authorization, because patents issuing on divisional applications which are filed to prosecute claims that the Examiner held to be independent and distinct can be vulnerable to legal challenges alleging double patenting. The third sentence of 35 U.S.C. § 121, which states that a patent issuing on a parent application “shall not be used as a reference” against a divisional application or a patent issued thereon, does not provide comfort to applicants against such allegations. The Court of Appeals for the Federal Circuit has declined to hold that 35 U.S.C. § 121 protects a patentee from an allegation of same-invention double patenting, Studiengesellschaft Kohle mbH v. Northern Petrochemical Co., 784 F.2d 351, 355, 228 U.S.P.Q. 837, 840 (Fed. Cir. 1986); and in Gerber Garment Technology Inc. v. Lectra Systems Inc., 916 F.2d 683, 16 U.S.P.Q. 2d 1436 (Fed. Cir. 1990), that court held that §121 does not insulate a patentee from an allegation of “obviousness-type” double patenting, and in fact affirmed the invalidation on double patenting grounds of a patent that had issued from a divisional application filed following a restriction requirement. Furthermore, it is far from clear that the step of filing a terminal disclaimer is available to resolve a double patenting issue that arises after the issuance of a patent on the divisional application.

All these considerations indicate that the imposition of these two restriction requirements

with inadequate authority can lead to situations in which an applicant's legitimate patent rights are exposed to uncertainty and even extinguished. Accordingly, to protect a patentee's rights and to serve the public's interest in the legitimacy of issued patents, applicants respectfully urge the Examiner not to require restriction in cases such as the present application wherein various aspects of a unitary invention are claimed.

In addition, the Courts have recognized the advantages to the public interest to permit patentees to claim all aspects of their invention, as the applicants have done herein, so as to encourage the patentees to make a more detailed disclosure of all aspects of their invention. The CCPA has observed:

We believe that the constitutional purpose of the patent system is promoted by encouraging applicants to claim, and therefore to describe in the manner required by 35 U.S.C. § 112 all aspects of what they regard as their invention, regardless of the number of statutory classes involved.

In re Kuehl, 456, F.2d 658, 666, 177 U.S.P.Q. 250, (CCPA 1973).

Furthermore, applicants respectfully request that in view of increased Official Fees and the potential limitation of applicants' financial resources, a practice, which arbitrarily imposes a Restriction Requirement, may become prohibitive, and thereby contravenes the constitutional intent to promote and encourage the progress of science and the useful arts.

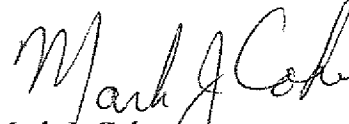
Further, applicants respectfully submit that a determination to make the pending restriction requirement final must evidence the patentable distinctness of the groups and species, one from another, as presented in the Office Action.

Hence, it is respectfully requested that the Examiner reconsider and withdraw the



Restriction Requirement, and provide an action on the merits with respect to all of the claims and to the full scope of the subject matter being claimed.

Respectfully submitted,

A handwritten signature in cursive script, appearing to read "Mark J. Cohen".

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